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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------------|
| 10/523,000 | 11/18/2005 | Neil David Watkins | 1781-0016 | 4665 |
| 28078 7590 09/26/2007 MAGINOT, MOORE & BECK, LLP CHASE TOWER 111 MONUMENT CIRCLE SUITE 3250 INDIANAPOLIS, IN 46204 | | | EXAMINER SIGLER, JAY R | |
| | | | ART UNIT 3709 | PAPER NUMBER |
| | | | MAIL DATE 09/26/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,000

Applicant(s)

WATKINS ET AL.

Examiner

Jay R. Sigler

Art Unit

3709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 3, 4, 6 and 8 is/are rejected.
- 7) ☒ Claim(s) 5 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02 February 2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the mixing tool must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters:

- a. "9" and "20" have both been used to designate a sealing component;
- b. "23" and "63" have both been used to designate a sensor;
- c. And, "32" and "54" have both been used to designate the bone cavity.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet; even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in

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upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

4. Claim 4 is objected to because of the following informalities: in the phrase "in which the plug which can be received", the second "which" should be removed for clarity. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 2, 3, 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (U.S. Patent 5,842,785) in view of Cohen et al. (U.S. Patent 5,980,527) and Draenert (U.S. Patent 4,671,263).

Concerning claim 1, Brown et al. teaches an instrument (Figure 1 and 4) for deploying a bone cement material in a bone cavity, the instrument comprising: a chamber 1 in which the components of the material can be mixed; a mixing tool 5 which extends into the chamber, and which can be manipulated from outside the chamber, to cause the components of the material to mix (Column 5, Lines 48-50); an outlet (at the end of part 1 where the nozzle 12 is attached) from the chamber through which the mixed material can be discharged from the chamber after it has mixed; a piston 3 which can be moved through the chamber to apply positive pressure to mixed material within the chamber, to displace the mixed material from the chamber through the outlet into a bone cavity (Column 5, Lines 12-15).

Brown et al. probably does not teach a sealing component which fits over the bone cavity or a sensor.

Cohen et al. teaches a sealing component (Figure 1), to be used with a device for adding bone cement to a bone cavity (Column 5, lines 19-22), which fits over a bone cavity to allow the pressure to be maintained on the cement throughout the period in which it hardens, as preferred for secure bonding of the cement to the bone (Column 6, Lines 60-63). It would have been obvious to

someone of ordinary skill in the art at the time of the invention to use the sealing component of Cohen et al. with the invention of Brown et al. to allow the pressure to be maintained on the cement throughout the period in which it hardens, as preferred for secure bonding of the cement to the bone.

Draenert teaches a device for applying bone cement (see Title) that includes a sensor (Column 5, Lines 41-44; taken to be embodied by a pressure gauge) to control the pressure during application (Column 5, Lines 41-44). It also would have been obvious to someone of ordinary skill in the art at the time of the invention to add the sensor of Draenert to the invention of Brown et al. to control the pressure during application.

Concerning claim 2, Draenert further teaches the sensor being in the chamber (Column 5, Lines 41-44; taken to be embodied by the pressurized zone) or on the piston (Column 5, Lines 48-50).

Concerning claim 3, the pressure sensor of Draenert would be close to any face of the sealing component of Cohen et al. when combined with the invention of Brown et al. The definition of close being taken as being near in space (close. 2003. In *The American Heritage® Dictionary of the English Language*. Retrieved September 18, 2007, from <http://www.credoreference.com/entry/4074086>).

Concerning claim 4, Cohen et al. further teaches the sealing component comprises: a sealing plate which can be fitted over the bone cavity and has a quantity of a resiliently deformable material on its lower face to enable a seal to

be created between the plate and the edge of the bone (Claim 1); and a plug which has an injection port extending through it in which the outlet (Claim 1, taken to be embodied by the injection nozzle of bone cement delivery apparatus) can be received, the sealing plate having an opening extending through it in which the plug can be received, and through which a prosthesis which is to be bonded to the bone of the cavity by the bone cement can be inserted into the cavity after injection of the cement and removal of the plug (Claim 1).

Concerning claim 6, Draenert further teaches the pressure sensor generates a signal which is representative of the pressure to which the bone cement is subjected during displacement from the chamber, and in which the signal gives rise to an indication of the said pressure which is visible (Column 5, Lines 46-47 and Column 12, Lines 49-53; taken to be embodied by the color rings indicate the existing pressure and the pressure is adjusted manually to the desired value indicated by a color marking of the pressure gauge).

Concerning claim 8, Draenert also teaches the pressure sensor generates a signal which is representative of the pressure to which the bone cement is subjected during displacement from the chamber (as shown above), and in which the signal can be arranged to cause the pressure that is applied to the bone cement by the piston to be changed when the pressure is outside a pre-determined range (Column 5, Lines 46-48 and Column 12, Lines 49-53; taken to be embodied by the color markings for the correct pressure to be a pre-

determined, or desired, range and that they would cause an operator to manually change the pressure when outside this range).

Allowable Subject Matter

7. Claims 5 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or fairly suggest the limitations in claims 5 and 7. For example, the prior art does not teach locating the pressure sensor in the sealing plate or in which the pressure sensor causes a warning signal to be generated when the pressure to which the bone cement is subjected during displacement from the chamber is less than about 3 kPa.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jay R. Sigler whose telephone number is (571) 270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

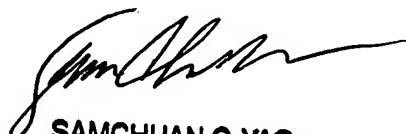
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



18 september 2007
jrs



SAMCHUAN C. YAO
SUPERVISORY PATENT EXAMINER